Section 5 – 510(k) Summary

General Information

Owner's Name: N.M. Beale Company, Inc.
Address: 89 Old Shirley Road
Harvard, MA 01451
Telephone Number: (978) 456-6990
Fax Number: (978) 456-3927
Contact Person: Nathaniel Beale

Subject Device Name: PEF Tube
Trade Name: PEF Tube
Common/Usual Name: Gastrointestinal tube & accessories
Product Code: KNT – Gastrointestinal tube & accessories
FDA Regulation: 21 CFR 876.5980 – Gastrointestinal tube & accessories
Device Classification: Class II

Predicate Device Name: Bard Dreiling Tube
Trade Name: Dreiling Tube (Bard Medical, Inc.)
Common/Usual Name: Gastrointestinal tube & accessories
Product Code: KNT – Gastrointestinal tube & accessories
FDA Regulation: 21 CFR 876.5980 – Gastrointestinal tube & accessories
Device Classification: Class II
Premarket Notification: Unknown

Device Description
The PEF Tube consists of a soft, dual-lumen tube with a proximal Y-connector that allows separate access to each of the 2 lumens. One lumen opens distally in the stomach; the second lumen opens into the duodenum.

Intended Use
For use in achieving simultaneous access to the stomach and duodenum to allow fluid sampling in procedures such as pancreatic exocrine function testing.

Performance Testing
Performance data demonstrated that the N.M. Beale Co., Inc. PEF Tube is substantially equivalent to the predicate device and/or met pre-determined acceptance criteria. Performance testing consisted of tensile testing.

Conclusion
The PEF Tube meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the PEF Tube is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

N. M. Beale Company, Inc.
c/o Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K071579
Trade/Device Name: PEF Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 14, 2007
Received: November 16, 2007

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K071579

Section 4 – Indications for Use Statement

510(k) Number (if known): _____

Device Name: PEF Tube

Indications for Use:

For use in achieving simultaneous access to the stomach and duodenum to allow fluid sampling in procedures such as pancreatic exocrine function testing.

Prescription Use __X___ OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071579